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Filed : August 5, 2003

REMARKS

By way of summary, Claims 1-51 were pending in this application. Claims 1-4, 13, 14, 33, 34, and 40-51 have been withdrawn from consideration. In the outstanding Office Action, Claims 27 and 28 were allowed, Claims 5-9, 15-19, 21, 23-26, 29-32, 35, and 36 were rejected, and Claims 10-12, 20, 22, and 37-39 were objected to as containing patentable subject matter but depending from a rejected independent claim. In this Amendment, Claims 5, 9, 10, 15, 26, and 29-32 have been amended, and Claim 52 has been added. Accordingly, Claims 1-52 remain pending.

Allowed Claims and Allowable Subject Matter

The Applicants gratefully acknowledge the Examiner's allowance of independent Claims 27 and 28 and the indication of allowable subject matter in Claims 10-12, 20, 22, and 37-39. Applicants respectfully submit, as explained below, that the remaining claims are also now in condition for allowance.

Claim Amendments

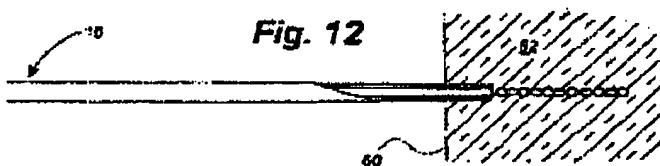
In this Amendment, Claims 5, 9, 10, 15, 26, and 29-32 have been amended to further define the subject matter for which protection is sought and to expedite issuance of a patent. Claims 5, 15, 26, 29, and 30 have been amended to recite, among other things, that the implant is biocompatible. Claim 5 has been amended to further define the biocompatible implants as being "sized and shaped to convey aqueous humor from the anterior chamber to a fluid outflow path of the eye so as to reduce elevated intraocular pressure." Claim 15 has been amended to further define the method and now recites, in part, "providing a plurality of biocompatible implants that, when implanted, convey aqueous humor from the anterior chamber to a fluid outflow path of the eye so as to reduce intraocular pressure." Claim 31 has been amended to further define the method for treating glaucoma and now recites, in part, "positioning said instrument at a first location and utilizing said instrument to deliver a first implant into the posterior segment of the eye at said first location," and, "moving said instrument to a second location and utilizing said instrument to deliver a second implant into the posterior segment of the eye at the second location." Claim 32 has been amended to further recite, "said dispensing comprising moving the instrument a respective plurality of times." Lastly, Claim 52 has been added by this Amendment.

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The Applicants respectfully submit that the claims as previously pending are patentably distinguished over the cited references or any combination thereof. The above-referenced claims, however, have been amended without altering their scope in order to clarify the features of the Applicants' inventions. These claim amendments are not made for patentability purposes, and it is believed that the claims would satisfy the statutory requirements for patentability without the entry of such amendments. Applicants reserve the right to pursue claims of the same or broader scope in a continuation application and respectfully submit that the pending claims are now in a condition for allowance.

§ 102 Rejection of Claims 5-9 by Mercereau

The outstanding Office Action rejected Claims 5-9 under § 102(e) as being anticipated by U.S. Patent No. 6,450,937 to Mercereau. Applicants respectfully submit that independent Claim 5, as amended, is not anticipated by Mercereau. Mercereau discloses a brachytherapy needle for delivering brachytherapy seeds into the body of a patient for localized radiation treatment of a tumor. Brachytherapy seeds are radioactive seeds that are implanted into the body near the tumor to kill the cancerous tissue, as illustrated in the figure of Mercereau reproduced in part



here. The brachytherapy needle is configured to carry the radioactive seeds within the lumen of the needle, and a pusher stylet is used to push the seeds from the distal end of the needle into or near the cancerous tissue.

Amended Claim 5 Not Anticipated by Mercereau

In contrast to the disclosure and teachings of Mercereau, independent Claim 5 now recites, in part, "a plurality of biocompatible implants positioned in the elongate body, each of said implants sized and shaped to convey aqueous humor from the anterior chamber to a fluid outflow path of the eye so as to reduce elevated intraocular pressure." Applicants respectfully submit that, being cytotoxic, the radioactive seeds of Mercereau are biodestructive, not biocompatible, and that the seeds are not sized and shaped to convey aqueous humor from the anterior chamber to a fluid outflow path of the eye so as to reduce elevated intraocular pressure.

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Accordingly, Applicants respectfully submit that independent Claim 5, as amended, is not anticipated by Mercereau and respectfully request the anticipation rejection based on Mercereau to be withdrawn.

Amended Claim 5 Not Obvious in View of Mercereau and Other References

Additionally, Applicants respectfully submit that independent Claim 5, as amended, is not rendered obvious by Mercereau. Mercereau is a nonanalogous reference, and thus, the teachings of Mercereau should not be considered for obviousness purposes. A reference is analogous if the reference is "in the field of applicant's endeavor or, if not, [the reference is] reasonably pertinent to the particular problem with which the inventor was concerned."¹ The field of the Applicant's endeavor is the treatment of glaucoma, while Mercereau's field of endeavor is radiation therapy for cancer, and thus, Mercereau is not in the field of the Applicants' endeavor. Additionally, the particular problem with which the Applicants were concerned was the implantation of multiple biocompatible implants in multiple locations within into the eye, in which the implants convey aqueous humor from the anterior chamber to a fluid outflow path of the eye so as to reduce elevated intraocular pressure. In contrast, Mercereau addressed the problem of the implantation of radioactive seeds in a single location. The implantation of radioactive seeds in a single location would not have logically commended itself to an inventor looking to treat glaucoma with biocompatible implants that convey fluid from the anterior chamber to a fluid outflow path of the eye so as to reduce elevated intraocular pressure.² Accordingly, Mercereau is nonanalogous art and should not be considered for purposes of obviousness.

Applicants respectfully submit that Mercereau also teaches away from consideration in combination with the teachings of glaucoma therapy references, including the references cited in the outstanding Office Action (i.e., U.S. Patent No. 6,533,768 to Hill and Publication No. 2003/0088260 to Smedley). Mercereau teaches the implantation of radioactive seeds to kill

¹ M.P.E.P. § 2141.01(a) (I) (citing *In re Oetiker*, 977 F.2d 1443, 1446, 24 U.S.P.Q.2d 1443, 1445 (Fed. Cir. 1992)).

² See M.P.E.P. § 2141.01(a) (I) (citing *In re Clay*, 966 F.2d 656, 659, 23 U.S.P.Q.2d 1058, 1060-61 (Fed. Cir. 1992) ("A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem.")).

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tumors in the body of a patient. The implantation of *non-biocompatible* radioactive seeds that destroy body tissue teaches away from the implantation of biocompatible implants that enhance and facilitate the function of body tissue (i.e., draining of aqueous humor from the eye). Accordingly, Mercereau teaches away from combination with implantation of biocompatible implants, and its teachings should not be combined with those of glaucoma references teaching the implantation of biocompatible implants for consideration of obviousness.

Inasmuch as Mercereau does not disclose, teach, or suggest a plurality of biocompatible implants that are sized and shaped to convey aqueous humor from the anterior chamber to a fluid outflow path of the eye so as to reduce elevated intraocular pressure and, as explained above, the combination of the teachings of Mercereau with those of glaucoma treatment would be improper, Applicants respectfully request indication of allowance of Claim 5.

Dependent Claims 6-9

Claims 6-9 depend from amended Claim 5, and Applicants respectfully submit that the dependent claims are patentable for at least the same reasons set forth above with respect to Claim 5 in addition to the patentable subject matter contained in each dependent claim. Accordingly, Applicants respectfully request withdrawal of the anticipation rejections of dependent Claims 6-9.

§ 103 Rejection of Claims 15-19, 21, 23-26, 29-32, 35, 36, and 39 by Smedley

The outstanding Office Action rejected Claims 15-19, 21, 23-26, 29-32, 35, 36, and 39 as being unpatentable over Smedley. The Office Action states, regarding Smedley, that "using the device [of Smedley] to implant another implant at another location in Schlemm's canal without withdrawing the instrument from the eye is not disclosed." Office Action, page 4. The Office Action then relies on Mercereau for the teaching of introducing multiple implants, stating that it would have been obvious to "take advantage of the plurality of collector channels (see para. 111) which would facilitate the passage of aqueous out of the eye which would prevent unwanted increase in internal ocular pressure." Page 4. Applicants respectfully submit that the above-listed claims are not rendered obvious by Smedley and Mercereau.

Applicants respectfully submit that it is improper to combine the teachings of Smedley, which provides disclosure on glaucoma implants for reducing intraocular pressure, and

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Mercereau, which discloses the implantation of radioactive seeds for brachytherapy. Not only is Mercereau nonanalogous art, but, as explained above, Mercereau teaches away from combining its teachings with that of a reference disclosing methods of treating glaucoma. Additionally, the combination in the Office Action fails to consider the substantial reconstruction and redesign of the Smedley implants in addition to the change in the basic principle of operation that would be required in order to combine the teachings of the references.³

For example, one substantial change in the principle of operation is the maintenance of proper orientation during implantation. Mercereau does not disclose any means for keeping the radioactive seeds oriented in a particular direction, and, in fact, it does not need to disclose such a means because the implanted seeds are spherical and do not have a preferred orientation. However, the implants of Smedley have a specific orientation in which they must be implanted into the eye. Even if the teachings of Mercereau and Smedley were combined, it is not clear how the delivery device would maintain the proper orientation of each implant. Unlike Mercereau, it does not appear that the implants could be dropped serially into the delivery device without consideration of how to keep the implants properly oriented during deployment. Such a consideration would require a substantial reconstruction of both the Smedley and Mercereau devices and would change the basic principle of operation under which Smedley currently deploys the devices. Accordingly, Applicants respectfully submit that the combination of the teachings of Smedley and Mercereau are improper and do not sustain the obviousness rejection of Claims 15-19, 21, 23-26, 29-32, 35, 36, and 39.

Furthermore, to combine the references would require impermissible hindsight derived from the teachings in the present application, and not the teachings of the prior art. The Federal Circuit reiterated the importance of "particularly identifying any suggestion ... to combine ...

³ See M.P.E.P. § 2143.02(VI) ("If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.") (It is an improper combination when the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate.").

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references," to avoid what the court deemed as "hindsight-based obviousness analysis." See In re Dembiczak, 175 F.3d 994 (Fed. Cir. 1999).⁴

Similar to Dembiczak, the Applicants respectfully submit that there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the teachings of Smedley in combination with the teachings of Mercereau. The Office Action suggests that the motivation is to "take advantage of the plurality of collector channels (see para. 111) which would facilitate the passage of aqueous out of the eye which would prevent unwanted increase in internal ocular pressure." Page 4. Paragraph 111 of Smedley, however, discusses, in part, other places into which the outlet section of the single implant may be placed. Specifically, the relevant portion of the paragraph states, "In other embodiments, the outlet section 9 may advantageously be placed into fluid communication with other natural outflow pathways, such as, but not limited to, aqueous collector channels, aqueous veins, and episcleral veins, as described above." While the paragraph discloses other outflow pathways, including collector channels, into which the outlet section of the single implant can be placed, Applicants respectfully submit that the above-referenced statement is directed to embodiments of placing the outlet section of the single implant and that the statement does not suggest deploying multiple implants to "take advantage of" the plurality of collector channels. Accordingly, Applicants respectfully submit that a *prima facie* case of obviousness was not established, which requires providing some suggestion or motivation, from the references or in the knowledge generally available to one of ordinary skill in the art, to modify the teachings of Smedley in combination with the teachings of Mercereau.

In addition to the reasons set forth above, Applicants respectfully submit that Claims 15–19, 21, 23–26, 29–32, 35, 36, and 39 are patentable over the cited references for at least the following additional reasons.

⁴ In Dembiczak, the Federal Circuit held that that the Board did not particularly identify a suggestion to combine, among other things, a design patent depicting a bag with a jack-o-lantern face, conventional plastic trash bags, and a book showing how to make a paper bag pumpkin by stuffing a trash bag full of newspapers. The Court reiterated that a determination of obviousness cannot simply rely on the inventor's disclosure as a "blueprint" without evidence of a suggestion, teaching or motivation in the prior art. Therefore, the Court did not allow the Board to sustain an obviousness rejection of claims to large trash bags resembling pumpkins or jack-o'-lanterns.

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Claims 15-19, 21, and 23-25

Amended independent Claim 15 now recites, in part, "utilizing said instrument to deliver a first biocompatible implant . . . at a first location," and, "utilizing said instrument to deliver a second biocompatible implant . . . at a second location, without removing said instrument from the eye between said deliveries of said implants." Applicants respectfully submit that Mercereau and Smedley, alone or in combination, do not disclose such a method. The disclosure of Mercereau is directed to placement of the brachytherapy seeds at a single location, and Smedley only discloses implantation of a single glaucoma implant. Accordingly, alone or in combination, Mercereau and Smedley do not disclose a plurality of implants delivered at a plurality of locations. Thus, Applicants respectfully submit that Mercereau and Smedley do not render amended independent Claim 15 obvious and respectfully request withdrawal of the obviousness rejection.

Dependent Claims 16-19, 21, and 23-25 depend from Claim 15, and Applicants respectfully submit that the dependent claims are patentable for the same reasons set forth above with respect to amended independent Claim 15 in addition to the patentable subject matter recited in each of the dependent claims. Accordingly, Applicants respectfully request withdrawal of dependent Claims 16-19, 21, and 23-25.

Amended Claims 26, 29, and 30

Amended independent Claims 26, 29, and 30 now recite, in part, "utilizing said instrument to deliver a first biocompatible implant . . . at a first location; and utilizing said instrument to deliver a second biocompatible implant . . . at a second location." As stated above, Applicants respectfully submit that Smedley and Mercereau do not disclose, alone or in combination, a plurality of implants delivered at a plurality of locations. Accordingly, Applicants respectfully submit that Mercereau and Smedley do not render Claims 26, 29, and 30 obvious. Additionally, Claim 26 now recites, in part, "wherein said locations are determined from morphological data on a collector channel." Neither reference provides any disclosure, teaching, or suggestion that the locations are determined from morphological data on a collector channel. Smedley states that "the outlet section may advantageously be placed into fluid communication with other natural outflow pathways, such as, but not limited to, aqueous collector channels, aqueous veins, and episcleral veins," but this statement does not suggest that

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a plurality of implants are delivered at a plurality of location, which locations are determined from morphological data on a collector channel. Claim 30 now recites, in part, "wherein said implants have different flow characteristics." There is no disclosure, teaching, or suggestion in Smedley and Mercereau, alone or in combination, regarding the implantation of a plurality of implants at a plurality of location in which the implants have different flow characteristics. Accordingly, Applicants respectfully submit that Mercereau and Smedley do not render amended Claims 26, 29, and 30 obvious, and withdrawal of the obviousness rejections based on the same is respectfully requested.

Amended Claim 31

Amended Claim 31 now recites, in part, "utilizing said instrument to deliver a first implant . . . at said first location; and moving said instrument to a second location and utilizing said instrument to deliver a second implant . . . at the second location, without removing said instrument from the eye between said deliveries of said implants." Applicants respectfully submit that Smedley and Mercereau, alone or in combination, do not disclose, teach, or suggest implanting a plurality of implants at a plurality of locations in the eye for treating glaucoma without removing the instrument from the eye between deliveries of the implants. Accordingly, Applicants respectfully submit that Smedley and Mercereau do not render Claim 31 obvious, and withdrawal of the obviousness rejection of Claim 31 is respectfully requested.

Amended Claim 32

Amended Claim 32 now recites, in part, "serially dispensing a plurality of preloaded implants from an instrument into eye tissue at a respective plurality of locations within the eye, said dispensing comprising moving the instrument a respective plurality of times." Applicants respectfully submit that Smedley and Mercereau, alone or in combination, do not disclose, teach, or suggest implanting a plurality of implants at a plurality of locations within the eye and moving the instrument a respective plurality of times. Accordingly, Applicants respectfully submit that Smedley and Mercereau do not render Claim 32 obvious, and withdrawal of the obviousness rejection of Claim 32 is respectfully requested.

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§ 103 Rejection of Claims 15–18 by Hill

Amended independent Claim 15 was rejected in the Office Action as being unpatentable over Hill in view of Mercereau. As stated above, however, Applicants respectfully submit that it is impermissible to combine the teachings of Hill and Mercereau. Additionally, Applicants respectfully submit that Hill and Mercereau, alone or in combination, do not disclose the recited limitations of Claim 15. The disclosure of Mercereau is directed to placement of the brachytherapy seeds at a single location, and Hill discloses implantation of a single glaucoma implant. Accordingly, alone or in combination, Hill and Mercereau do not disclose a plurality of glaucoma implants delivered at a plurality of locations in the eye without removing the instrument from the eye between the deliveries of the implants. Thus, Applicants respectfully submit that Hill and Mercereau do not render amended independent Claim 15 obvious, and Applicants respectfully request withdrawal of the obviousness rejection.

Dependent Claims 16–18 depend from Claim 15, and Applicants respectfully submit that the dependent claims are patentable for the same reasons set forth above with respect to amended independent Claim 15 in addition to the patentable subject matter recited in each of the dependent claims. Accordingly, Applicants respectfully request withdrawal of dependent Claims 16–18.

CONCLUSION

In view of the foregoing, the present application is believed to be in condition for allowance, and such allowance is respectfully requested. Applicants have made a good faith effort to respond to the outstanding Office Action. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is cordially invited to contact Applicants' attorney, at the telephone number below, to resolve any such issues promptly.

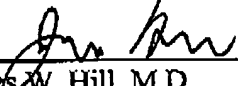
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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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